APR - 6 2004

K040127

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:

Debbie Schmitt
Cook Urological, Inc.
1100 West Morgan Street
Spencer, Indiana 47460

Device:

Trade Name:	Cook Ureteral Balloon Dilation Catheter Set (Not yet determined)
Proposed Classification Name:	Dilator, Catheter, Ureteral

Predicate Devices:
The Cook Ureteral Balloon Dilation Catheter Set is substantial equivalent to predicate devices in terms of indications for use and design. Predicate devices include the Balloon Ureteral Dilator Set, D.C. #K813278 manufactured by Cook Urological, Accent DG™ Balloon Ureteral Dilator Set, D.C. #K905375 manufactured by Cook Urololgical, Ascend™ Balloon Dilation Catheter, D.C. #K970041, the Balloon Dilation Catheters manufactured by Bard and the High Pressure Ureteral Dilatation Balloon Catheter manufactured by Microvasive.

Device Description:
The Cook Ureteral Balloon Dilation Catheter Set is used for dilation prior to ureteral stone manipulation or ureteroscopy, and dilating the intramural ureter. The materials used to construct the balloon and catheter is nylon with a hydrophilic coating. The Catheter is 7 French in diameter and is 65 cm's in length. The Rated Burst is 20 ATM's. The Set will include the balloon catheter and an inflation device. The product will be sold as sterile and intended for one-time use.

Substantial Equivalence:
The device will be manufactured according to specified process controls and Quality Assurance Program. The device will undergo packaging and sterilization procedures to devices currently marketed and distributed by Cook Urological. Being similar with respect to indications for use, materials and physical construction to predicate devices, this device meets the requirements for section 510(k) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 6 2004

Ms. Debbie Schmitt
Regulatory Affairs Manager
Cook Urological
1100 W. Morgan Street
SPENCER IN 47460

Re: K040127
Trade/Device Name: Cook® Ureteral Dilation Catheter Set
Regulation Number: 21 CFR §876.5470
Regulation Name: Ureteral dilator
Regulatory Class: II
Product Code: 78 EZN
Dated: March 10, 2004
Received: March 12, 2004

Dear Ms. Schmitt:

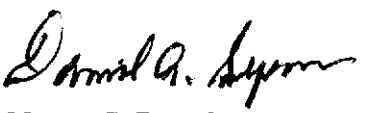
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~Not yet assigned~~ K040127

Device Name: Cook Ureteral Balloon Dilation Catheter

Indications for Use: The Cook Ureteral Balloon Dilation Catheter Set is used for Dilation prior to stone manipulation or ureteroscopy, and Dilating the intramural ureter. This device is sterile And intended for one-timeuse.

Prescription Use ✓ OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040127